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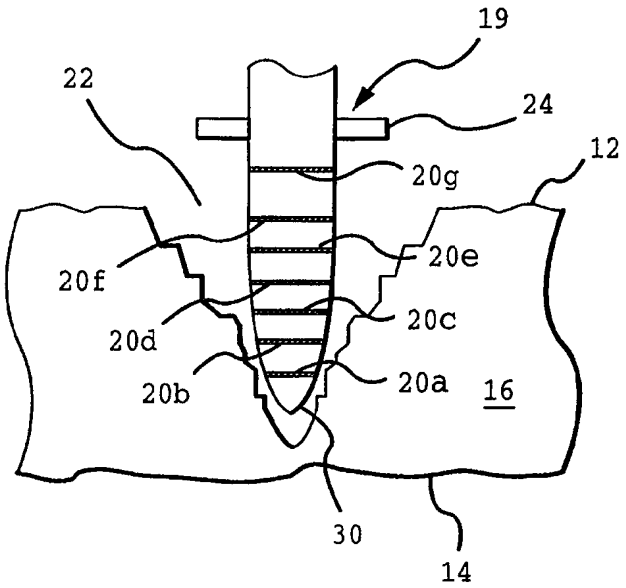

(57) Abstract

This invention is an electro–surgical device (19) and method for transmyocardial revascularization. A device having electrodes (20a–20g) can be inserted into the body of a patient to penetrate the patient's heart (16). Activating the electrodes forms a channel within the heart through which blood can access. The channel ca be tapered (30) so that it is wider at the endocardium than at the epicardium. Different embodiments of the device may be introduced into the interior of the heart through vasculature, or can be used from exterior the heart. The device can be used to create a serpentine channel within the heart, and to create a channel in the septum.

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RADIO FREQUENCY TRANSMYOCARDIAL REVASCULARIZATION

FIELD OF THE INVENTION

The present invention relates to medical treatment of the heart muscle, and more particularly to transmyocardial revascularization using radio frequency (RF) and other ablation techniques.

BACKGROUND OF THE INVENTION

A number of treatment options exist for cardiovascular disease. These include medical treatment with drugs, various forms of interventional therapy such as balloon angioplasty and atherectomy devices, and bypass surgery. Some treatments, such as bypass or transplant surgery, are major medical procedures that entail significant risks to a patient during the surgical operation. In the case of transplants, a patient may have to wait for a prolonged period of time before another heart is available. For these and many other reasons, alternatives to major surgery are desirable. Such alternatives may be intended as comprehensive treatments or as palliative measures to sustain a patient until other treatments are available.

The present invention relates to transmyocardial revascularization (TMR). TMR is a procedure where one or more channels are made in the heart, in order to allow blood to perfuse into the channels and thereby relieve the effects of disease. As used herein, the "heart" primarily refers to the muscular tissue of that organ, but can include any part of the organ. Such a procedure is generally described in, among other places, U.S. Pat. Nos. 5,125,924 (Rudko, 1992) and 5,125,926 (Rudko et al., 1992), which describe a pulsed laser system that purportedly overcomes problems associated with forming channels in a beating heart. Laser implemented TMR (also called laser myocardial revascularization or LMR) is also described in U.S. Pat. Nos. 5,389,096 (Aita et al., 1995) and 5,554,152 (Aita et al., 1996), which describe the use of an elongate flexible lasing apparatus to form channels within the heart. Pat. No. 5,389,096 describes creating a channel from the interior of the heart (endocardium) towards the exterior (epicardium), and stopping the channel before the epicardium is penetrated. Pat. No. 5,554,152

describes creating a channel from the epicardium through the heart endocardium and myocardium.

None of the known prior art discloses TMR techniques that are not dependent upon a laser. U.S. Pat. No. 4,658,817 (Hardy, 1987) uses a combination of laser energy and mechanical penetration. While lasers may result in satisfactory TMR, they have a number of drawbacks. It is difficult to supply adequate power from external to a body, through a catheter, and to the lasing element. Shaping laser beams is difficult, if at all possible; indeed, none of the known prior art discloses a shaped channel in connection with TMR. Further, none of the prior art discloses steering a TMR apparatus in relation to the heart.

Electrosurgical devices have been developed that ablate tissue or other objects by the application of radio frequency (RF) current. See U.S. Pat. No. 5,454,809 (Janssen, 1995). While electrosurgical devices are disclosed, there is no teaching to suggest adapting such devices for TMR. The present invention overcomes limitations in TMR by providing an alternative device and method of use for forming channels within the heart. As used herein, the term "catheter" is used to refer to devices inserted through vasculature and "probe" is used to refer to devices insertable through more invasive procedures; however, the terms may be used somewhat interchangeably and are not intended to restrict the invention disclosed herein in any way. The contents of all documents referred to herein are hereby incorporated by reference.

SUMMARY OF THE INVENTION

The present invention is a device and a method of use to effect transmyocardial revascularization. A catheter or probe has one or more electrodes positioned on a distal end for supplying current to ablate a portion of the heart of a patient, thereby creating a channel. The channel allows blood to perfuse the heart, which has been found to improve its function. Selecting the shape of the device, the waveform generated by the electrodes, or both allows selection of the shape of the channel; preferably it is tapered so that it is wider nearer the center of the heart chamber. Different embodiments allow for the channel to be created from the inside of the heart (after inserting a catheter to the inside of the heart through the patient's

vasculature) or from the outside of the heart. An angled arm may be used to allow access to desired locations of the heart when the device is used from outside of the heart.

A channel may be created within the septum of the heart as well as the myocardium. Further, a serpentine channel may be created by steering a device according to the present invention through the heart, allowing for more blood to perfuse the treated area.

Different waveforms may be used, and the application of the waveforms can be synchronized with the mechanical or electrical parameters of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic view of a heart and an embodiment of the present invention.

FIGS. 2, 3, and 4 are elevation views of distal tips of embodiments of the present invention inserted within a heart.

FIG. 5 is perspective view of an aspect of the present invention having forward ablation capability positioned adjacent a heart.

FIGS. 6 and 6A are elevation views of embodiments of the present invention having a tapered distal end.

FIGS. 7, 8, and 9 are sequential elevation views of an embodiment of the invention penetrating a heart and being withdrawn therefrom.

FIG. 7A shows optional electrodes added to the embodiment of FIG. 7.

FIG. 10 is a perspective view of an embodiment of the present invention for forming a tortious channel within a heart.

FIGS. 10A, 10B, 10C, and 10D are schematic views of the embodiment of the invention of FIG. 10 creating a tortious channel within a heart.

FIGS. 11, 11A, and 11B are schematic views of an embodiment of the present invention creating a channel within a septum within a heart.

FIGS. 12, 12A, 12B, and 12C show embodiments of the invention having an arm to access the heart.

FIGS. 12D and 12E show side views of visualization techniques useful with the present invention.

FIGS. 13, 13A, 13B, and 13C show representative waveforms that are useful with the present invention.

FIGS. 14A, 14B, and 14C show profile views of probe end shapes according to an aspect of the invention.

FIG. 15 shows an elevation view of a template according to the present invention.

FIGS. 16 and 16A show a perspective view and side view respectively of probes having multiple electrodes according to the present invention

FIGS. 17, 17A, 18, 18A, 19, and 19A are side views of embodiments of the present invention having ablating elements introduced into a myocardium through a hollow needle.

FIGS. 20 and 21 are a retracted and expanded side view respectively of an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides apparatus and methods to improve the flow of blood to the heart muscle. This is done by forming one or more channels within the heart muscle, thereby perfusing the heart with blood and reducing the effect of coronary disease. The channels are formed by RF or other electrical ablation techniques. Several techniques and related apparatus are disclosed, which are described below in turn.

With reference to FIG. 1, a heart 10 has an inner surface, the endocardium 12; an outer surface, the epicardium 14; and muscular tissue, the myocardium 16, therebetween. In one aspect of the invention, a catheter 19 is inserted into a ventricle 18 of the heart 10 through vasculature 8. The catheter 19 may be externally manipulated through the vasculature 8 to the ventricle 18 by the use of a guidewire or other techniques. The catheter 19 is used to create one or more channels 22 in the myocardium 16, which allow blood to enter these channels in the myocardium and thereby improve the operation of the heart.

Referring now to FIG. 2, the catheter 19 has a distal tip 30 that is capable of piercing the endocardium 12 so that a section of the catheter 19 penetrates into the myocardium 16. A series of RF electrodes 20, the electrodes being annular bands

20a-20g, are spaced around the body of the catheter 19 along a section of the catheter 19 proximal to the tip 30. The RF electrodes 20 can be selectively activated, either by a user or by a computer or other control, and supply a current to ablate a portion of the myocardium 16 and thereby create the channel(s) 22.

FIG. 3 shows the myocardium 16 after the electrodes 20 have been activated to create the channel 22. In this embodiment, the channel is created by energy that can ablate material up to a specified distance away from the electrode. The RF energy supplied to the electrodes 20 closer to the tip 30 is preferably less than the RF energy supplied to the electrodes 20 further from the tip 30. Stated another way, the energy supplied to electrode 20a is less than the energy supplied to electrode 20b, which is less than the energy supplied to electrode 20c, and so on. This creates a generally conical channel 22, that tapers down in size from the channel 22 portion at the endocardium 12 (widest) to the end closest to the epicardium 14 (narrowest). In this example, the electrode 20g is not activated at all, since it is proximal to the endocardium. The taper may have the shape of a series of steps, wherein each step corresponds to the location of an electrode 20, and intermediate portions of the channel 22 between steps correspond to the area between electrodes 20. Depending upon the energy delivered by the electrodes 20 to the myocardium 16 and the spacing between the electrodes 20, the steps may vary in size, or the channel 22 may be substantially smooth.

The tapered channel 22 is believed to be superior to the cylindrical channels that are known to the prior art. The smaller size of the channel 22 near the epicardium 14 reduces the chance of completely puncturing the epicardium 14, and reduces the damage to the heart 10 that would result if the channel 22 were to penetrate the epicardium 14. The relatively larger size of the channel 22 at the endocardium 12 allows an adequate supply of blood to perfuse the myocardium 16. Further, a conical shape allows for less bulk to be removed from the myocardium 16 than does a cylindrical shape of equal cross section at the endocardium 12. However, it should be appreciated that RF electrodes could be used to create a cylindrical channel if desired, by supplying equal energy to all electrodes, and that is an aspect of the present invention.

FIG. 4 shows the catheter 19 inserted within a myocardium 16' between a epicardium 14' and endocardium 12'. The myocardium 16' is somewhat thinner than the myocardium 16 previously discussed. In this case, only the electrodes 20a, 20b, and 20c have penetrated into the myocardium. Therefore only electrodes 20a-20c need be activated to create a channel in the myocardium 16'. It should be appreciated that electrodes 20a-20c may receive different energy levels than in the case of myocardium 16, because here the electrodes 20 will be creating a different channel section than in the case of myocardium 16. For example, electrode 20c is ablating the myocardium 16' section closest to the endocardium 12' section, whereas electrode 20f is ablating the myocardium 16 section closest to the endocardium 12. The present invention preferably includes a control to selectively allow a user to select the amount of energy the electrodes 20 receive.

Impedance sensing between the electrodes 20 can alert the user as to precisely which electrodes 20 are within the myocardium 20 and which are not. The impedance between two electrodes 20 that are both in the myocardium 20 will differ from the impedance between two electrodes 20 that are not in the myocardium 16, and from the impedance between one electrode 20 in the myocardium 16 and one not. By determining the impedance between each set of electrodes 20, the electrodes 20 that are in the myocardium 16 can be determined and only those electrodes 20 will be activated.

A stop 24 may be located on the catheter 19 somewhat proximal to the most proximal electrode, in this case electrode 20g. The stop 24 may be a protrusion on the catheter 20 that prevents the tip 30 from being over-inserted into the myocardium 16. Should the stop 24 be contacted against the endocardium 12, the stop 20 would prevent the catheter from being further inserted into the myocardium 16.

An alternative tip for penetrating the heart wall and forming a chamber therein may be shaped other than as described above, and may have one or any number of electrodes. Different tip embodiments are depicted in FIGS. 14A-14C. In FIG. 14A, a distal tip 30a has a generally concave curvature tapering to a pont. In FIG. 14B, a distal tip 30b is substantially cylindrical. In FIG. 14C, a distal tip 30c has a generally convex curvature. The various shapes in FIGS. 14A-14C will provide

different shaped channels within a patient's heart wall, and may be selected to achieve the desired channel. Electrodes are not depicted in FIGS. 14A-14C because, as noted above, various electrode configurations may be used.

Referring now to FIG. 5, an alternate embodiment of the invention is disclosed. The catheter 40 of FIG. 5 has electrodes 42a, 42b, 42c, and 42d. Each of the electrodes 42 has a component that ablates radially away from the catheter 40 (similar to the electrodes 20) and a portion that ablates along the catheter 40 axis, and distal to a catheter tip 44. The catheter 40 can be introduced into the myocardium 16 by activating the electrodes 42 when the catheter tip 44 is proximate the endocardium 12. This will ablate a portion of the endocardium, creating a void. The catheter 40 may then be advanced into the void, and the electrodes 42 may again be activated to create another void. The catheter 40 could simply be withdrawn after a channel of the desired depth is created. Alternatively, the catheter 40 may have additional electrodes 46a, 46b, and 46c that are annular bands similar to the electrodes 20 described above. The electrodes 46 can be activated when the catheter 40 has been inserted a desired depth into the myocardium 16 in order to a create a channel similar to the channel 22. It should be understood that the specific electrode configuration of the catheter 40 (and other embodiments of the invention described herein) is an example only and could be substantially modified without departing from the invention. For example, the electrodes 42 could be more or less than four in number. Indeed, one electrode may provide satisfactory results. Also, a center electrode could be positioned on the distal tip 44. As another example, more or fewer than three annular electrodes 46 could be used.

Another embodiment of the invention is described in connection with FIG. 6. This embodiment uses radial pressure to enable ablation, with the ablating electrodes being in contact with the material being ablated. A catheter 60 has a conical section 64 that tapers down in cross section to a distal tip 65. The conical section 64 can be inserted into the myocardium 16 similarly to the embodiment of FIG. 2, that is, the tip 65 is contacted against the endocardium 12 and pressure is applied to force the conical section 64 into the myocardium 16. A stop 67 located proximal to the conical section may be used to prevent the catheter 60 from being

inserted further into the myocardium 16 beyond a predetermined distance, so that the epicardium is not penetrated.

Annular electrodes 62a - 62f are spaced about a conical section 64 of the catheter 60. After the conical section is inserted within the myocardium 16, the electrodes 62 may be activated to create a channel such as channel 22. The channel will have a conical shape because it is created substantially around the conical section 64. In this embodiment, the electrodes 62a - 62f can apply approximately equal energy per unit area, i.e, energy density, in contrast to the embodiment of FIG. 2. The more proximal electrodes (e.g., 62f) may still apply somewhat more energy than the more distal electrodes (e.g., 62a), because they must ablate a larger cross section. Also, the embodiment of FIG. 6 allows for each electrode 62 to be somewhat closer to the myocardium 16 section that is being ablated. In the embodiment of FIG. 2, the more proximal electrodes are somewhat further from the myocardium 16 once the myocardium section immediately adjacent to the catheter 19 has been ablated. As in the other embodiment, the embodiment of FIG. 6 can be used with only some of the electrodes 62 inserted within the myocardium 16, as in FIG. 4.

With reference to FIG. 6A, a similar embodiment of a catheter has a tapered distal tip 200 and spaced annular electrodes 202a - 202e. Five electrodes 202 are shown merely as an illustrative number; more or fewer can be used. The more distal electrodes 202 are wider (that is, extend further in the longitudinal direction with respect to the catheter axis) than are the more proximal electrodes 202. Thus electrode 202a is wider than electrode 202b, which is wider than electrode 202c, and so on. The varying width is selected so that each electrode 202 has an equal (or approximately equal) area. Because of the taper of the tip 200, the more distal electrodes 202 have a smaller cross section (that is, their radial dimension with respect to the catheter axis) than the more proximal electrodes 202, the widths of the electrodes can be selected to achieve equal area. Equal area electrodes 202 allows for the same energy to be supplied to each of the electrodes 202, since they will ablate approximately the same amount of material. Stated another way, equal area electrodes allow the same energy supplied to the electrodes to result in the same energy density application. This may be advantageous in that it simplifies the

electronic control, among other reasons. However, it should be appreciated that energy may be intentionally supplied to the electrodes in equal or unequal amounts.

Another aspect of the invention is described in connection with FIGS. 7, 8, and 9. A probe 70 has a conical tip segment 72 terminating in a distal tip 73. Immediately proximal to the conical tip section 72 is an ablating segment 74. The ablating segment 74 is also conical in shape; however, the taper of the segment 74 is opposite the taper of the segment 72, so that the ablating segment is progressively narrower in the proximal direction. Electrodes 76a, 76b, 76c, 76d, 76e, and 76f are annular bands spaced around the ablating segment 74.

With reference to FIG. 7A, optional embodiments are shown. The tip segment 72 may have a sharp, needle type tip 91 to facilitate movement of the probe. Additionally, the tip 72 segment may have one or more electrodes 93, preferably annular rings, for the same purpose.

The embodiment discussed in connection with FIGS. 7-9 is used to create a channel 80 in the myocardium 16. The probe 70 is introduced into the myocardium 16 through the epicardium 14, rather than through the endocardium 12. Thus, the probe 70 is not introduced through the vasculature 8. Instead, the probe may be placed against the epicardium 14, as in FIG. 7, through any open heart procedure, related surgical technique, or minimally invasive surgery.

The probe is inserted through the epicardium 14, through the myocardium 16 and at least partially through the endocardium 12, as in FIG. 8. The insertion is performed at least until the distal end of the ablating segment 74 is substantially level with the endocardium 12. The insertion is facilitated by the shape of the conical tip 73 and tip segment 72- (and, optionally, the needle tip 91 and electrode(s) 93).

The myocardium 16 section proximate the ablating segment 74 approximately has the desired shape of the channel 80 when the probe has been inserted as described above (as in FIG. 8). This is because the myocardium is somewhat elastic and stretches to accommodate the span of the probe 70. The electrodes 76 are activated to ablate the myocardium 16 adjacent to the electrodes 76. By selecting the waveform, the myocardium 16 can be cauterized (or otherwise ablated) to maintain the conical shape of the ablating segment 72. At this time, the

probe 70 is withdrawn from the myocardium, again through the epicardium 14. The channel 80 remains having the conical shape of the ablating segment 72 (see FIG. 9), even after the probe 70 is withdrawn, because of the elastic quality of the myocardium 16. A hole 81 may exist at the end of the channel 80 near the epicardium 14, although the hole tends to close (and may completely close) because of the elasticity of the myocardium. If necessary, the hole 81 may be sealed by pressure, or by applying an appropriate waveform from one of the electrodes 93 (if present).

Another method of sealing the hole 81 uses an optional extendable trailing wire 77 attached to the distal tip 73. The trailing wire 77 is capable of supplying current to seal the hole. The wire 77 is extended after the channel 80 has been formed, as in FIG. 9. Activating the wire 77 causes an inflammation in the epicardium 14 around the hole 81, which reduces the size of the hole 81, or eliminates it entirely. The hole 81 may be sealed by a blood clot that forms upon the application of current from the wire 77, which may over time heal and form more permanent fibrotic material. The wire 77 may reside within the distal tip 73 during insertion of the tip 73, and be extended therefrom only when the tip 73 is withdrawn from the heart (similar to the deployment and retraction of a guide wire). It should be apparent that the trailing wire 77 is similar in function and purpose to the electrodes 93, merely providing another electrode platform. They may be used in any combination with one another.

Depending upon the location of the heart 10 that is to be treated, a curved or angled probe according to the present invention may facilitate access to the desired location. With reference to FIG. 12, a probe 160 may have a substantially straight section 162 and an arm 164 extending from the straight section. An ablating tip 165 is situated on the arm 164. The ablating tip 165 may be any embodiment described herein, such as, for example, the tip of the probe 70 described above. The position of the tip 165 on the arm 164 allows for side and rear positions of the heart 10 to be reached from an incision made generally in the front of a patient. In this embodiment, the arm 164 extends at approximately a right angle from the straight section 162.

Related embodiments are shown in FIGS. 12A, 12B, and 12C. In FIG. 12A, a probe 170 has a straight section 172 and an arm 174 extending from the straight section 172. An ablating tip 175 similar to the tip 165 is positioned on the arm 174. The arm 174 forms an obtuse angle with the probe 170. This embodiment allows for a somewhat different area of the heart 10 to be accessed than does the embodiment of FIG. 12. In the embodiment of FIG. 12B, a probe 180 has a curved arm 184 that extends from a straight section 182. An ablating tip 185 similar to the tip 165 is positioned on the arm 185. The arm 184 is curved more than 90 degrees in relation to the straight section 182, forming an acute angle. This curved arm 184 allows access to a different position of the heart 10 than the above embodiments. In the embodiment in FIG. 12C, a probe 190 has an angled arm 194 that extends from a straight section 192. An ablating tip 195 similar to the tip 165 is positioned on the arm 195. The arm 194 angles more than 90 degrees in relation to the straight section 192, as in the embodiment of FIG. 12B. The two embodiments are similar, except that FIG. 12B is curved whereas the embodiment of FIG. 12C is straight. The embodiments may provide somewhat different accessability. It should be understood that probes having different shapes than described may also be used and are part of the present invention, as the concept of using a curved or angled probe has been disclosed to allow access to the heart.

Probes as disclosed in FIG. 12-12C may be used in conjunction with minimally invasive or "keyhole" surgery, which involves making relatively small incisions as compared to a large thoracotomy. Further, such probes, and, indeed, any aspect of the present invention, may be used with visualization means such as, for example only not by way of limitation, fiber optics cable, or ultrasound transducers. In FIG. 12D, a probe 218 has an extendable visualization fiber optic cable 220 penetrating through an interior section of the probe. The probe 218 is meant to generically represent any of the embodiments of FIG. 12-12C, or any other embodiment of the invention. In FIG. 12E, a probe 228 (similar to probe 218) has an extendable visualization fiber optic cable 230 extending along an exterior wall of the probe 228. Such visualization techniques may assist a user in forming channels within the heart at desired locations.

Another aspect of the present invention is shown in FIG. 20. A probe 310 has an expandable distal end that can be expanded within a myocardium to create a tapered channel. The probe 310 is inserted in a retracted position, as in FIG. 20, and is expanded as shown in FIG. 21. A plurality of electrodes 304 are spaced about a section of the probe 310 and can be activated to form the tapered channel. The expansion may be accomplished by various methods; one such method is through the use of wires 306 that may be withdrawn and extended with respect to the probe 310. The probe 310 may be manufactured in the expanded shape of FIG. 21, and the wires 306 may be used to contract the probe 310 to the contracted shape of FIG. 20. It should be apparent that many other expansion techniques could be used with similar results.

Another embodiment of the invention is described in connection with FIGS. 10-10D. A steerable catheter is used to create a serpentine channel 110 in the myocardium 16. The serpentine channel allows a longer conduit of perfusion and thus provides more physiological substrate for angiogenesis. The catheter 100 has spaced electrodes 102a - 102d. Each of the electrodes 102 has a forward ablating component (i.e., distal to the probe 100 axis), and a side ablating component (i.e., radially away from the catheter axis). By activating all of the electrodes simultaneously, a void is created distal to the catheter 100 and the catheter 100 is advanced straight ahead. This is done to introduce the catheter 100 from the endocardium 12 to the myocardium 16 (see FIG. 10A). By selectively activating one (or more) of the electrodes 102, an asymmetrical void is created, and the catheter 100 can be advanced into the void, thus steering and turning the catheter 100. By repeating this procedure, a tortious path is created in the myocardium 16, as seen in FIG. 10C. The catheter 100 may then be withdrawn from the myocardium 16, leaving the serpentine channel 110, as seen in FIG. 10D.

Another aspect of the invention allows for the creation of channels within the septum of a heart. With reference to FIG. 11, a heart 120 has a heart wall 126 (comprising an epicardium, myocardium, and endocardium as described above), right ventricle 122 and a left ventricle 124 separated by a septum 128. A probe 130 has ablating electrodes 132 on a distal tip 134. The probe 130 can penetrate the heart wall 126 from exterior the heart at a point of insertion 127, and be

positioned against the septum 128, as shown in FIG. 11. The probe can be inserted through the heart wall 126 by application of external pressure or by RF energy, as described above.

After the probe 130 is positioned adjacent to the septum 128, it can be used to form a channel therein, as shown in FIGS. 11A and 11B. The distal tip 134 is inserted into the septum 128 (FIG. 11A). The electrodes 132 are then activated to form a channel 136, and the probe is then withdrawn from the septum, leaving the channel 136 intact. The probe can then be reinserted into another section of the septum to create another channel, and the process repeated to create a desired number of channels.

After the desired number of channels are created, the probe 130 can be withdrawn from the ventricle 124. The hole created at the point of insertion 127 of the probe 130 into the ventricle may be sealed by pressure, the application of RF energy to seal and cauterize the hole, or by other suitable means (see FIG. 11B). For example, a trailing wire similar to the wire 77 of FIG. 9 may be used.

The penetration of the septum has been described as going from the left ventricle 124 to the septum 128. However, the probe 130 may also be used to penetrate from the right ventricle 122 towards the septum 128. Further, any of the above described probes or catheters may be used to form the channel within the septum 128. As a specific example, a catheter may be inserted through vasculature leading to the heart, similarly as described in reference to the catheter 19 of FIG. 1, and used to create a channel or channels within the septum 128. In fact, the catheter described in FIG. 1 (or any of the other embodiments described herein) may be used to create channels within the myocardium, as described above, as well as the septum.

Another aspect of the invention is described with reference to FIG. 15. A template 250 has a plurality of through-holes 251 disposed thereon. In operation, the template 251 is placed on the epicardium 14. Thereafter, a probe according to any embodiment described herein (for, example, the probe of FIG. 7) is used to form a channel within the heart the myocardium 16 by accessing the epicardium through one of the through-holes 251. Next, the probe is used to form a channel through another one of the through-holes 251. Thus, the template 250 allows for a

series of holes to be created in a predetermined pattern. The pattern is selected by the arrangement of holes 251 on the template 250, and may be any desired pattern.

Another embodiment of the invention is described with reference to FIG. 16. A probe 260 has a distal end 262 from which a plurality of ablating elements 264 extend. Each ablating element 262 may include an electrode configuration, shape, and other aspects according to any probe described herein. The plurality of ablating elements 264 are used to create a plurality of channels within a patient's myocardium. The channels will have the same shape as the arrangement of the elements 264 on the end 262; the elements 264 may be placed in any desired arrangement to create any desired channel arrangement.

FIG. 16A depicts a similar embodiment, showing an alternative electrode arrangement. Here a probe 266 has a plurality of thin electrodes 268 extending therefrom. In operation, the embodiment of 16A is similar to the embodiment of FIG. 16. The primary difference is that the electrodes 268 are thinner than the electrode elements 262, to form corresponding thinner channels.

Three additional aspects of the invention are described with reference to FIGS. 17-19. In FIG. 17, a probe includes a hollow needle 280 encasing an electrode 282. The electrode 282 terminates at a tip 284 that is angled with respect to the needle 280. As shown in FIG. 17, the needle 280 has been inserted within the myocardium 16 of a patient. After the needle 280 has been inserted into the myocardium 16 to a desired depth, it is withdrawn, as in FIG. 17A. The electrode tip 284 remains in the myocardium 16 after removal of the needle 280, because the angle of the tip 284 resists, to a degree, retracted motion. It should be appreciated that the needle 280 is coupled to the electrode 282 to allow relative motion therebetween. Current is supplied through the electrode 282 to the tip 284 to ablate a portion of the myocardium 16. The electrode 282 may then be withdrawn, upon application of suitable force to overcome the resistance of the tip 284, resulting in a channel in the myocardium 16.

A similar embodiment of the invention is shown in FIG. 18. A probe includes a hollow needle 290 encasing an electrode 292. The electrode 292 terminates at a barbed tip 294. The barbed tip 294 is similar to the angled tip 282, except that the barb 294 is angled in two opposing directions. After the needle 290 has been

inserted in to the myocardium 16 to a desired distance, it is withdrawn, as in FIG. 18A. The barbed tip 294 remains in the myocardium because of its barbed configuration. Current is supplied to the based tip 294 to ablate a portion of the myocardium 16, thus forming a channel in the myocardium 16. The barbed tip 294 will, in general, require more force to withdraw than the angled tip 284, which is the primary difference between the two embodiments.

Another embodiment of the invention is shown in FIG. 19. A probe includes a hollow needle 300 encasing an electrode 302. Here the electrode terminates at a tip 304 that is merely the end of a wire that forms the electrode 302; that is, the electrode 302 is substantially a straight wire. After the needle 300 has been inserted into the myocardium 16, the electrode 302 may be advanced (see FIG. 19A), and current supplied to ablate an area around the electrode tip 304. The needle 300 and electrode 302 may then be removed form the myocardium 16. The primary difference between this embodiment and the embodiments of the FIGS. 17 and 18 is that the needle 300 is not withdrawn prior to ablation.

The invention includes particular waveforms and other electrical characteristics generated from the electrodes used in the various embodiments. The waveforms may be DC (direct current) pulses. The power supply may be one or more capacitors, or other suitable power supplies. Choosing a suitably high power supply, and a low impedance electrode circuit, allows for a desired power output. The shape of the waveform can be controlled by RLC circuit elements or active circuit elements as is known in the art.

Waveforms believed to be particularly effective are described in connection with FIGS. 13 - 13C, which are graphs of current as a function of time. FIG. 13 depicts a Lown wave, in which one positive phase of sinusoid is applied followed by one damped negative phase. FIG. 13A depicts a trapezoidal wave, where a single positive pulse is applied that has a decreasing current over time. FIG. 13B depicts a mono-phase square wave, where a constant-current pulse is applied for a period of time. FIG. 13C depicts a bi-phase square wave, where a uniform positive constant-current pulse is followed by a uniform negative constant-current pulse of the same magnitude.

It may be desirable to quickly form the above described channels within the heart, such as in less than about 100 milliseconds, although other channel formation rates may also be used. RF or other electrical energy may be applied. The energy may be differently applied for different electrodes. Conversely, it may be applied with different parameters at different times during treatment, e.g., it may be applied differently at the beginning than at the end of a procedure, so as to produce an optimum residual channel for angiogenesis with minimal blood loss.

Another related aspect of the invention is the ability to synchronize the application of energy to various parameters of the heart. The synchronization may include reference to the mechanical beating of the heart. In this case, it may be desirable to activate the electrodes only during the resting period (diastole) of the heart, so that ablation is performed to the heart while it is stationary. As noted above, it may be desirable to form a channel within one heart cycle. The synchronization may also include reference to the electrical waves (Q, R, S, and T) of the heart. Further, the synchronization may include reference to both the mechanical and electrical heart cycles.

The above described apparatus and techniques are most preferably performed repeatedly to form a desired number of channels within the myocardium.

CLAIMS

What is claimed is:

1. An electrosurgical device of transmyocardial revascularization of a heart of a patient, comprising:

a catheter body having a distal end insertable through a section of vasculature of the patient to the location of the heart; and

an electrode situated proximate the catheter distal end for supplying current to the heart to ablate a portion of the heart to form a channel therein.

2. The device of claim 1, wherein the distal end terminates substantially at a point, whereby the distal end can penetrate the heart when a force is applied to the proximal end.

3. The device of claim 1, further comprising a plurality of electrodes situated on the distal end of the catheter.

4. The device of claim 3, further comprising means for sensing the impedance between the plurality of electrodes whereby the catheter position can be determined.

5. The device of claim 3, wherein each of the plurality of electrodes is substantially an annular band spaced about the catheter, the electrodes being arranged along a longitudinal length of the distal end of the catheter.

6. The device of claim 5, wherein each of the electrodes can be selectively activated to conduct a different current level from that of another electrode.

7. The device of claim 6, wherein the electrodes closer to the termination of the distal end conduct progressively lower amounts of current to create a taper to the channel.

8. The device of claim 5, wherein the catheter distal end is tapered along the length on which the electrodes are arranged, so that the channel will be tapered.

9. The device of claim 8, wherein each electrode has substantially equal area.

10. The device of claim 3, further comprising a stop located on the catheter proximal to the plurality of electrodes for preventing the insertion of the device into the heart past the stop.

11. The devise of claim 1, wherein the electrodes are capable of generating a waveform selected from the class consisting of Lown, trapezoid, mono-phase square, and bi-phase square.

12. The device of claim 1 further comprising means for visualization of the catheter.

13. The device of claim 1, wherein the visualization means include a fiber optic cable.

14. A device for transmyocardial revascularization of a heart of a patient, comprising:

a probe having a distal end, the distal end having a tip capable of penetrating a wall of the heart;

at least one electrode for ablating a portion of the heart wall to form a channel therein.

15. The device of claim 14, wherein the top tapers downward in cross section in the distal direction.

16. The device of claim 15, wherein the at least one electrode is on a section of the probe proximal to the tip that tapers downward in cross section in the proximal section.

17. The device of claim 16, further comprising a needle extending distal from said tip.

18. The device of claim 15, further comprising means for sealing the channel from an area external to the heart.

19. The device of claim 18, wherein the sealing means comprises a wire extendable from the tip, the wire capable of supplying current.

20. The device of claim 18, wherein the sealing means includes RF energy directable to coagulate a portion of the channel.

21. The device of claim 14, wherein the probe has a substantially straight section and an arm extending at an angle from the substantially straight section, the electrode being positioned on the arm for accessing a desired location of the heart.

22. An electrosurgical device for transmyocardial revascularization of a heart of a patient, comprising:

a catheter having a distal tip, the catheter being insertable within the patient; and

a plurality of electrodes situated proximate the distal tip, the electrodes being selectively activatable to asymmetrically ablate the heart thereby forming a serpentine channel in the heart.

23. The device of claim 22, wherein at least some of the plurality of electrodes have a component to ablate in a distal direction with respect to the catheter and a component to ablate in a radial direction with respect to the catheter.

24. The device of claim 23, wherein the catheter is an elongate member having an axis and at least one of the plurality of electrodes is substantially in line with the axis at an extreme distal end of the catheter.

25. A device for transmyocardial revascularization of a heart of a patient, comprising:

a probe having a distal end capable of insertion into the heart;

at least one electrode capable of ablating a septum within the heart.

26. A system for transmyocardial revascularization of a heart of a patient, comprising:

a probe having at least one electrode capable of supplying current to ablate a portion of the heart and form a channel therein, and

a template having a plurality of through-holes, the template capable of being placed on the heart so that the probe may be contacted with the heart through the through-holes.

27. A device for transmyocardial revascularization of a heart of a patient, comprising:

a probe having a distal end;

a plurality of electrodes extending from the probe distal end, so that the electrodes can be simultaneously contacted with the heart to form a plurality of channels there within.

28. A device for transmyocardial revascularization of a heart of a patient, comprising:

a hollow needle capable of at least partially penetrating the heart;

an electrode enclosed within the hollow needle, the electrode capable of supplying current to ablate a portion of the heart.

29. The device of claim 28, wherein the electrode has a tip angled with respect to the hollow needle.

30. The device of claim 29, wherein the electrode has a barb.

31. The method of transmyocardial revascularization of a heart of a patient comprising the steps of:

(a) inserting a catheter through a section of vasculature to the heart surface; and

(b) ablating a section of the heart to form a channel therein by activating a electrode situated on a distal end of the catheter.

32. The method of claim 31, wherein the step of ablating includes activating the electrode to generate a waveform selected from the class of Lown, trapezoid, mono-phase square, and bi-phase square.

33. The method of claim 31, further comprising the step of:

(c) inserting the distal end of the catheter into the heart.

34. The method of claim 33, wherein step (b) is performed before step (c).

35. The method of claim 33, wherein step (c) is performed before step (b).

36. The method of claim 33, wherein the catheter supports a plurality of electrodes, and the step of ablating a section of the heart includes supplying different amounts of current to the electrodes to create a taper to the channel.

37. A method of transmyocardial revascularization of a heart of a patient comprising the steps of:

(a) inserting a probe into the body of a patient to an exterior section of the heart; and

(b) ablating a section of the heart to form a channel therein by activating an electrode situated on a distal end of the probe.

38. The method of claim 37, further comprising the steps of inserting the distal end of the catheter into the body of the patient and withdrawing the probe from the body.

39. The method of claim 38, wherein the withdrawing steps and ablating steps are performed substantially simultaneously.

40. The method of claim 39, further comprising the step of sealing a hole created by the withdrawing step.

41. A method of transmyocardial Revascularization of a heart of a patient, comprising the steps of:

inserting a probe substantially to the surface of the heart;

ablating a section of the heart to create a void by activating an electrode on the probe;

inserting the probe into the void;

ablating another section of the heart to create another void;

advancing the probe into the another void;

repeating the above steps until a desired channel is formed within the heart; and withdrawing the probe from the heart of the patient.

42. The method of claim 41, wherein at least some of voids are created offset in relation to at least some other of the voids so that the channel is tortious.

43. A method of transmyocardial revascularization of the heart of a patient, comprising the steps of inserting a catheter into the heart and ablating a channel within a septum of the heart by activating an electrode situated on the catheter.

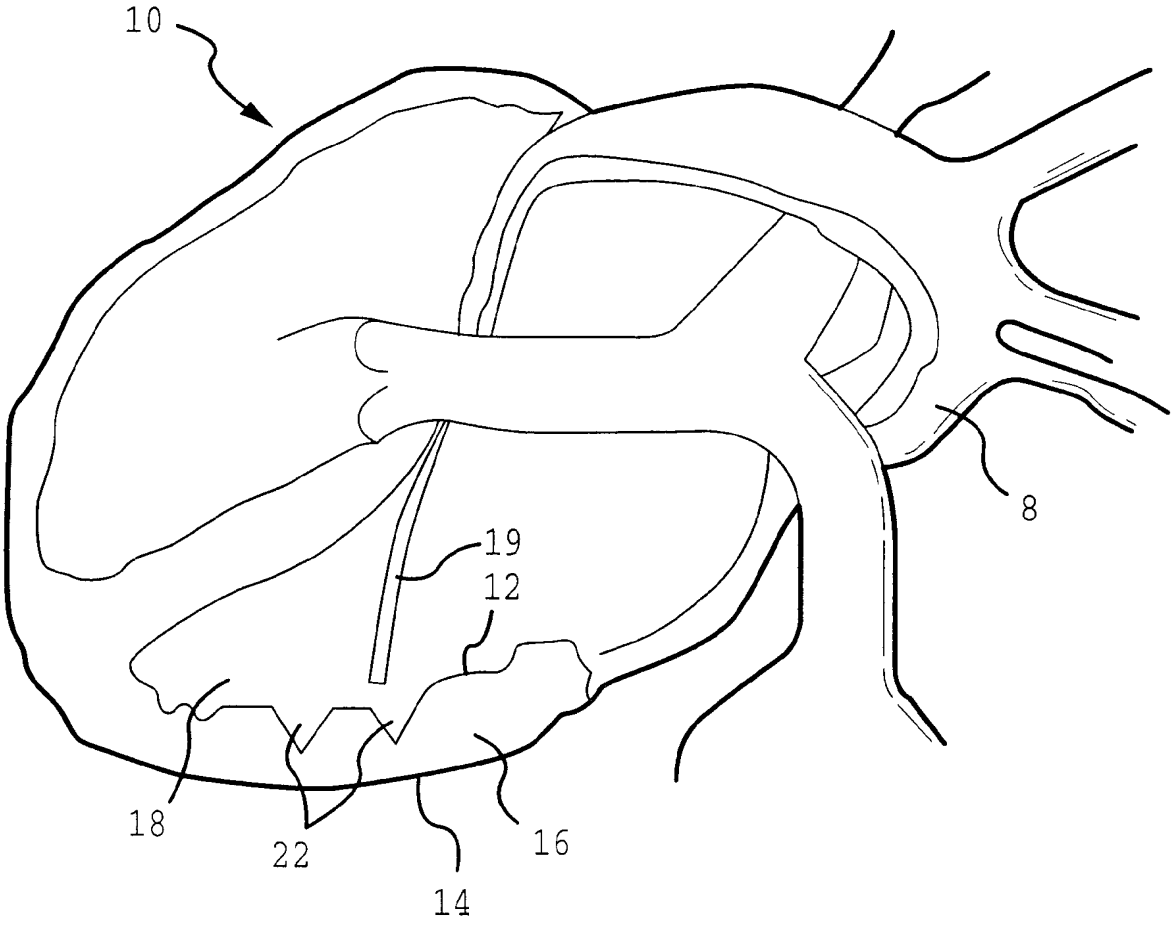
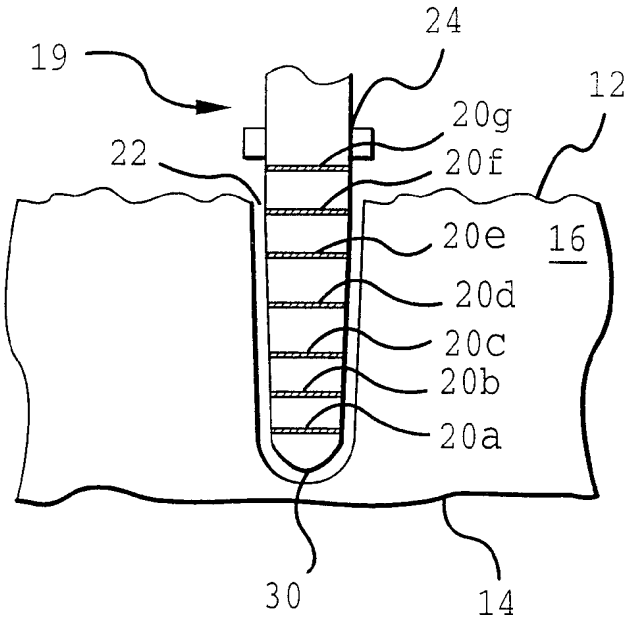


FIG.1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20c
20b
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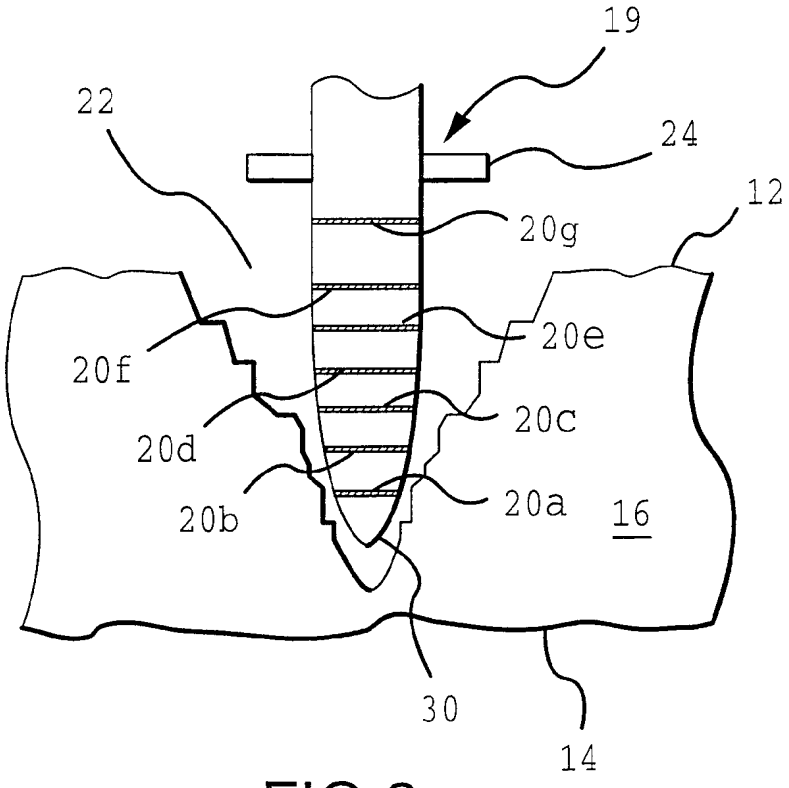
30
14

FIG.2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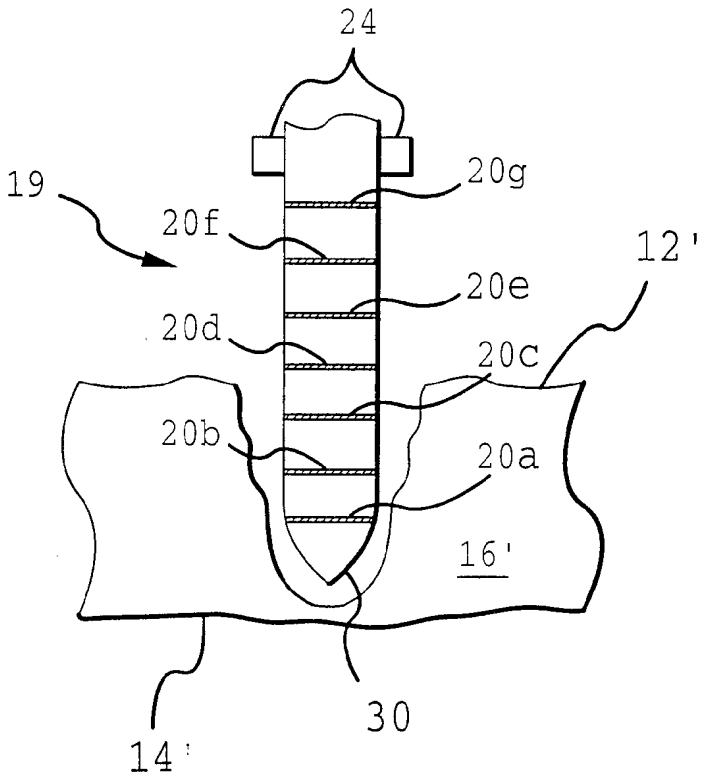
30
14

FIG.3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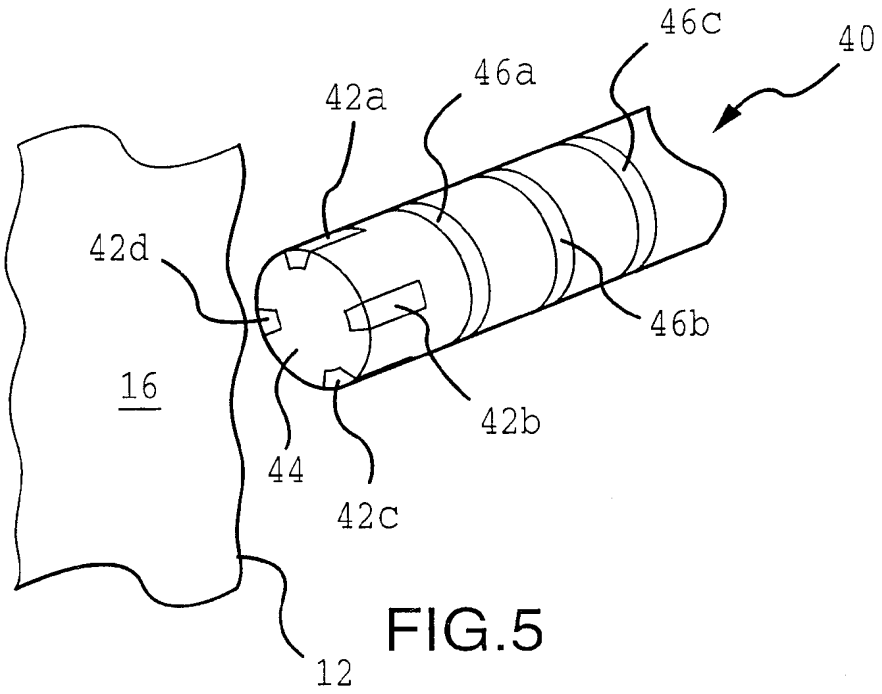
30
14'

FIG.4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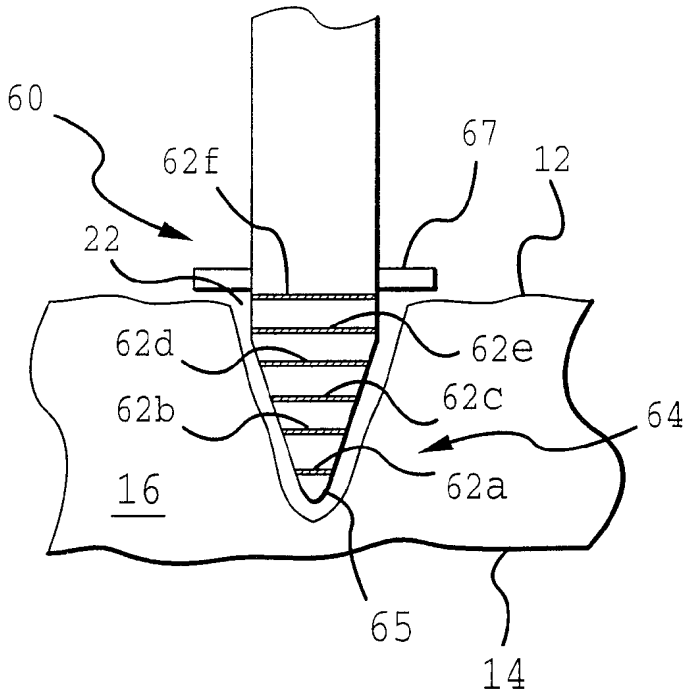
42a
42d
46b
16
42b
44
42c
12

FIG.5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14

FIG.6

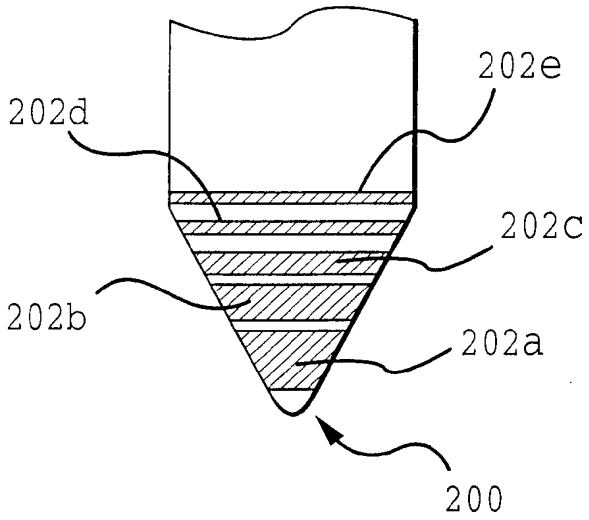
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FIG.6A

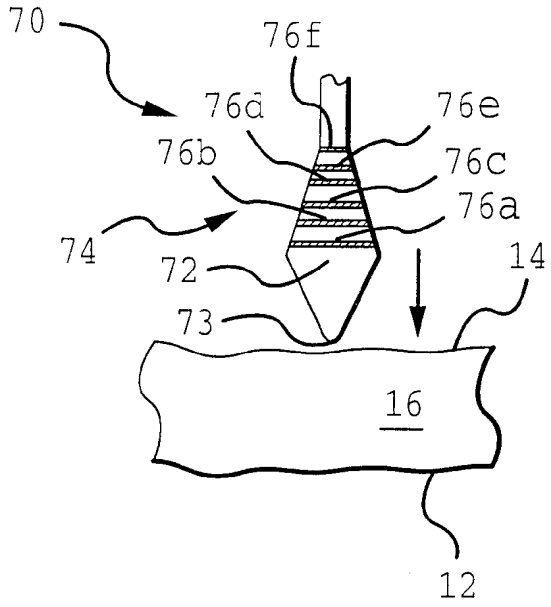

FIG.7

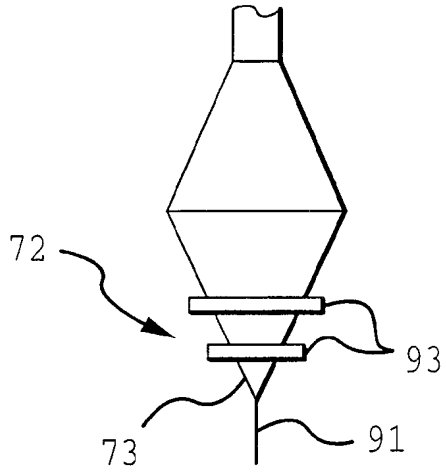

FIG.7A

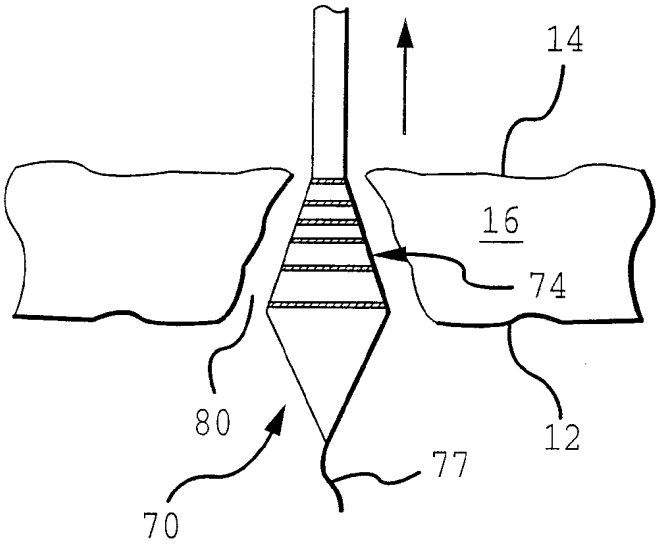

FIG.8

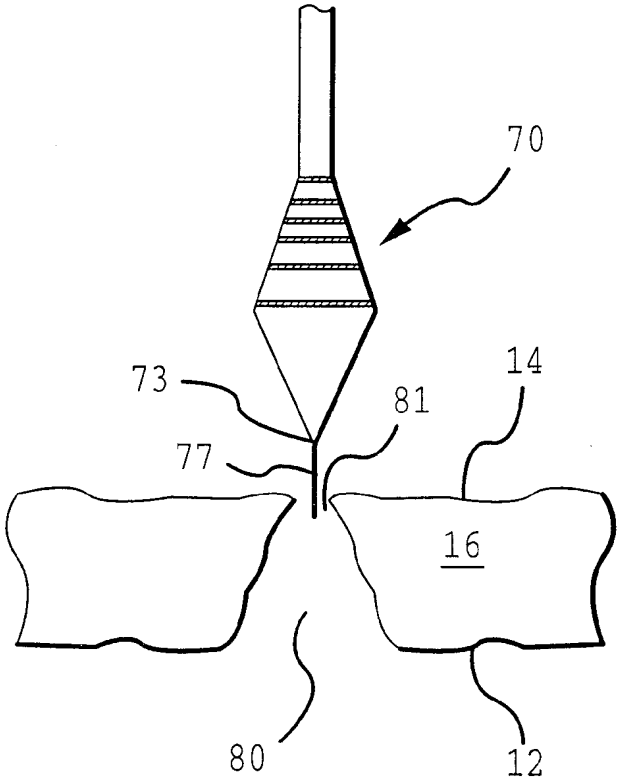

FIG.9

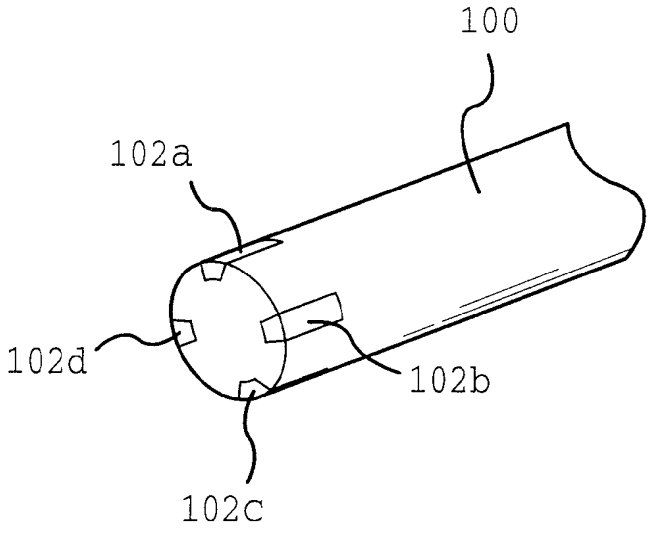

FIG.10

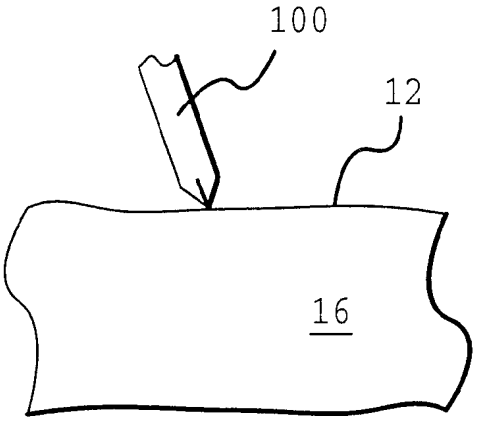

FIG.10A

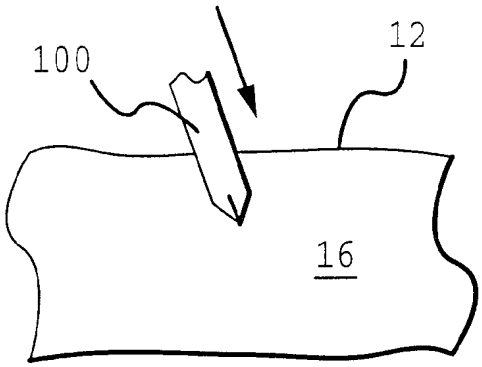

FIG.10B

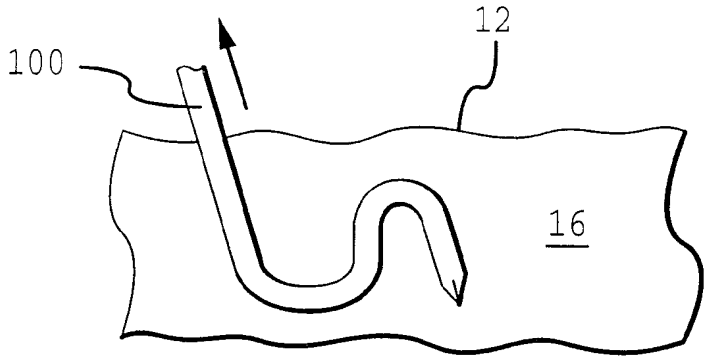

FIG.10C

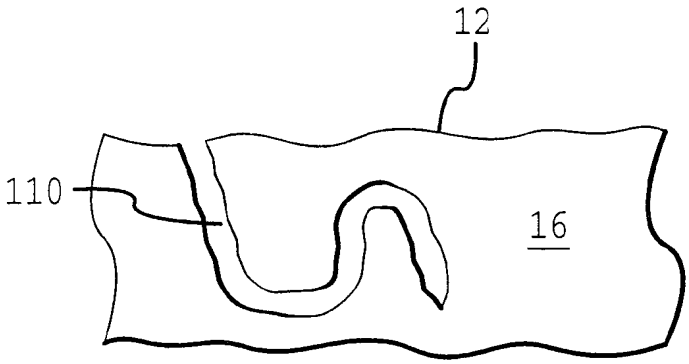

FIG.10D

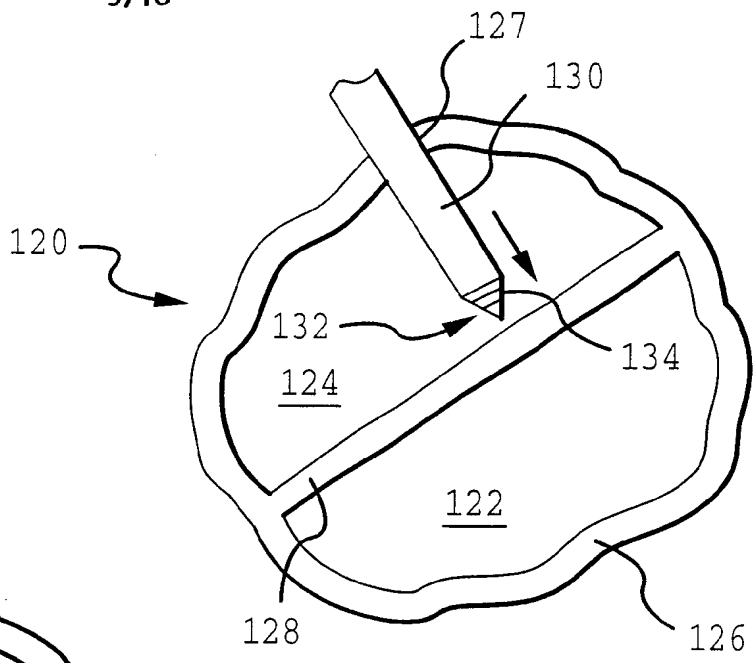

FIG.11

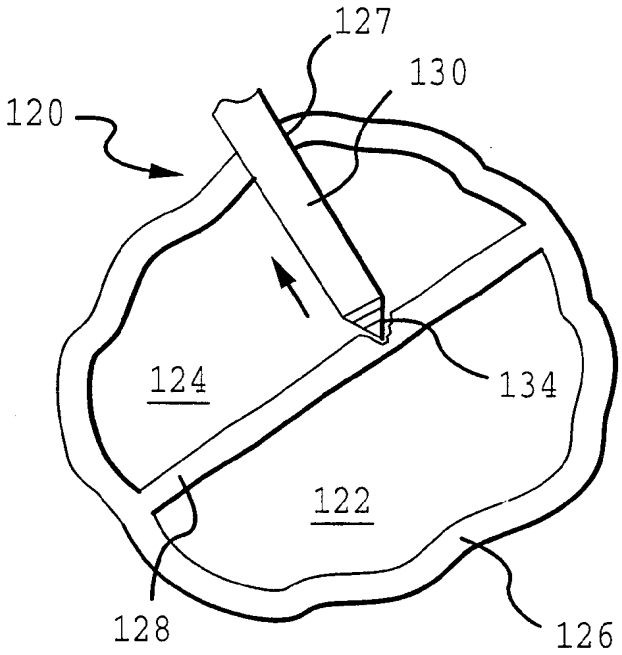

FIG.11A

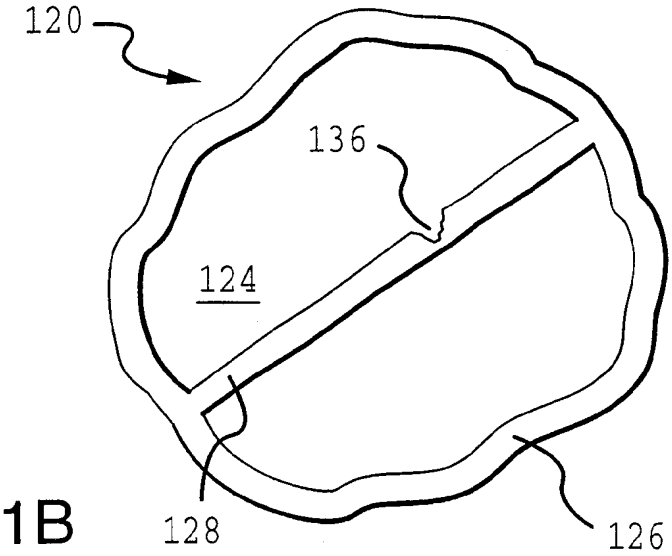

FIG.11B

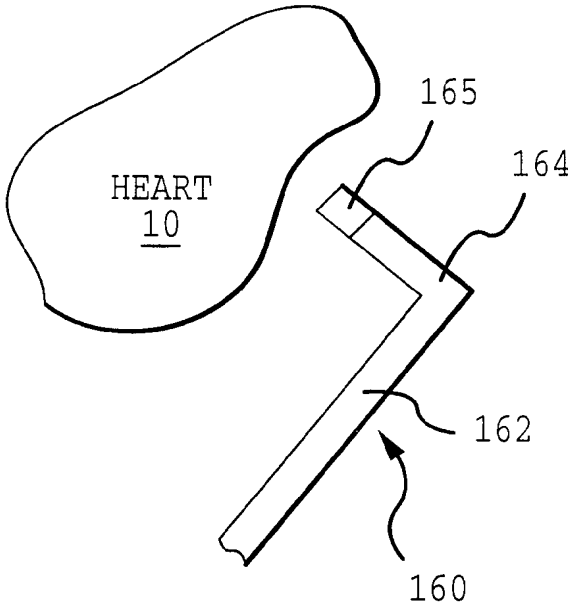

FIG.12

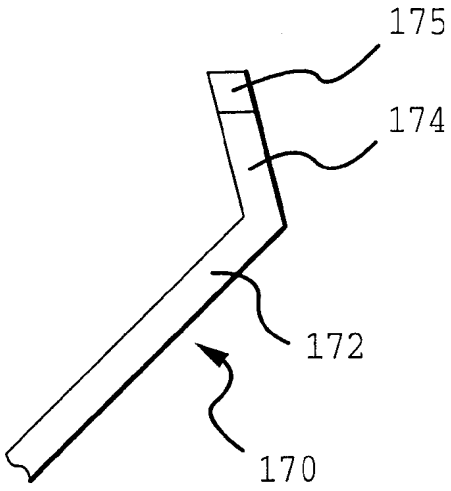

FIG.12A

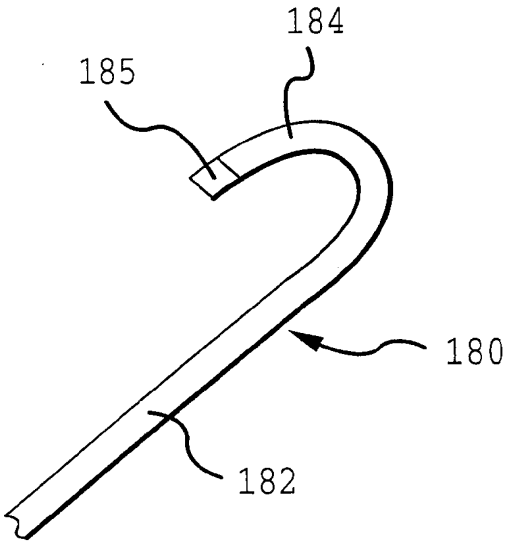

FIG.12B

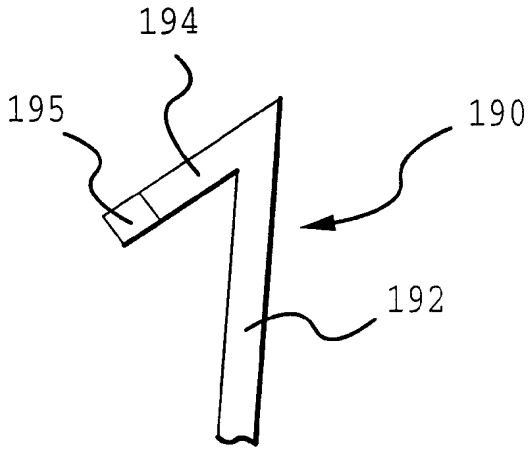

FIG.12C

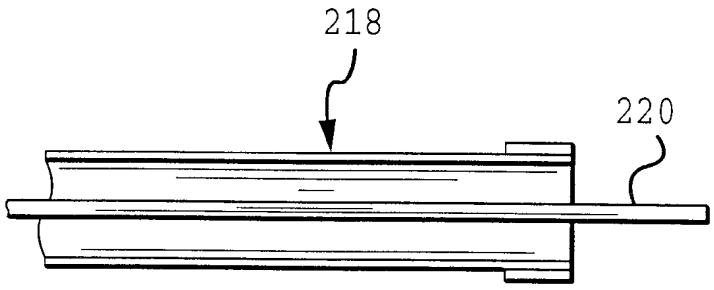

FIG.12D

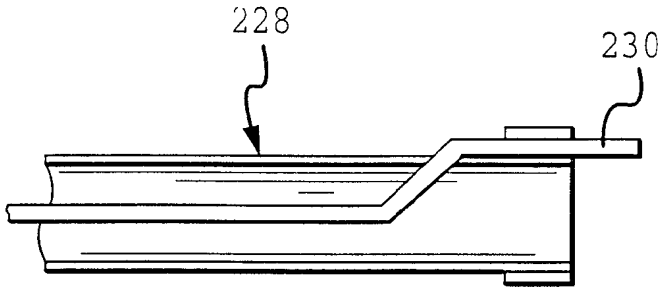

FIG.12E

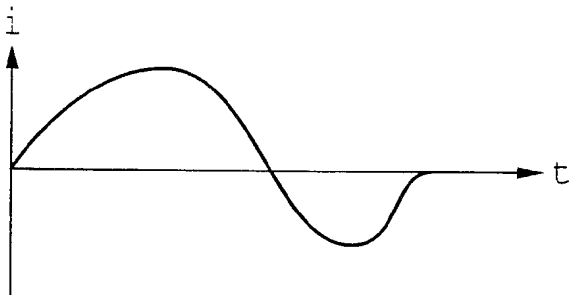

FIG.13

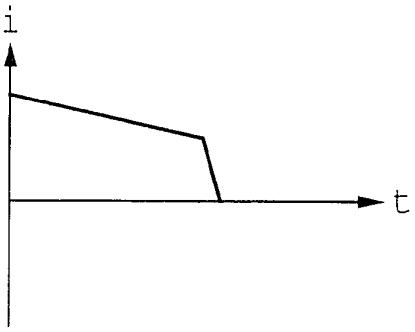

FIG.13A

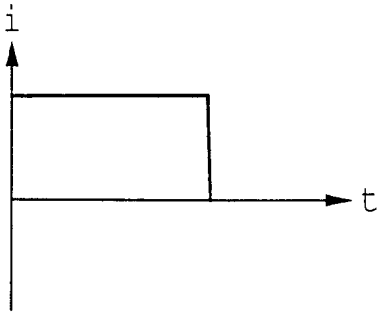

FIG.13B

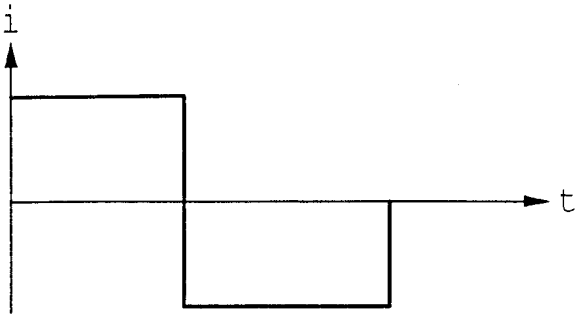

FIG.13C

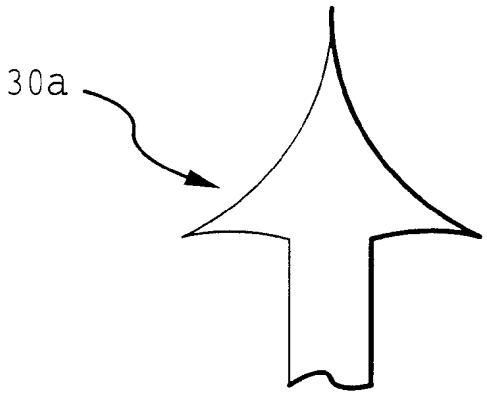

FIG.14A

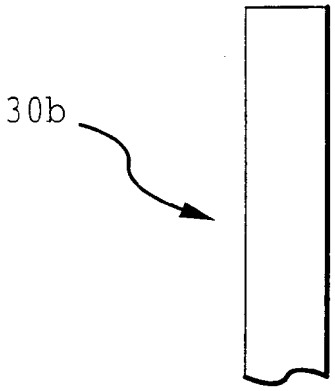

FIG.14B

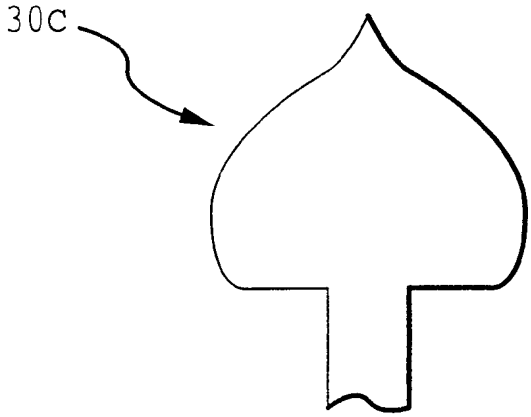

FIG.14C

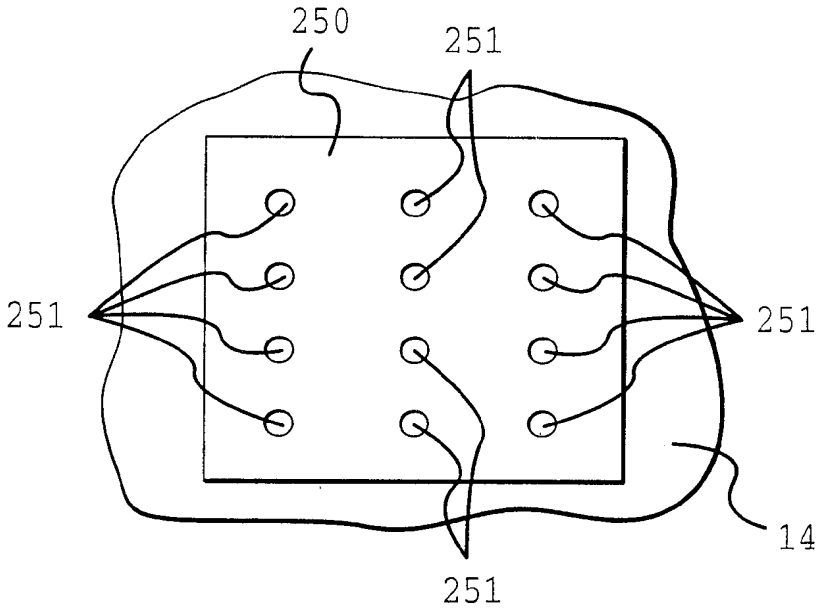

FIG.15

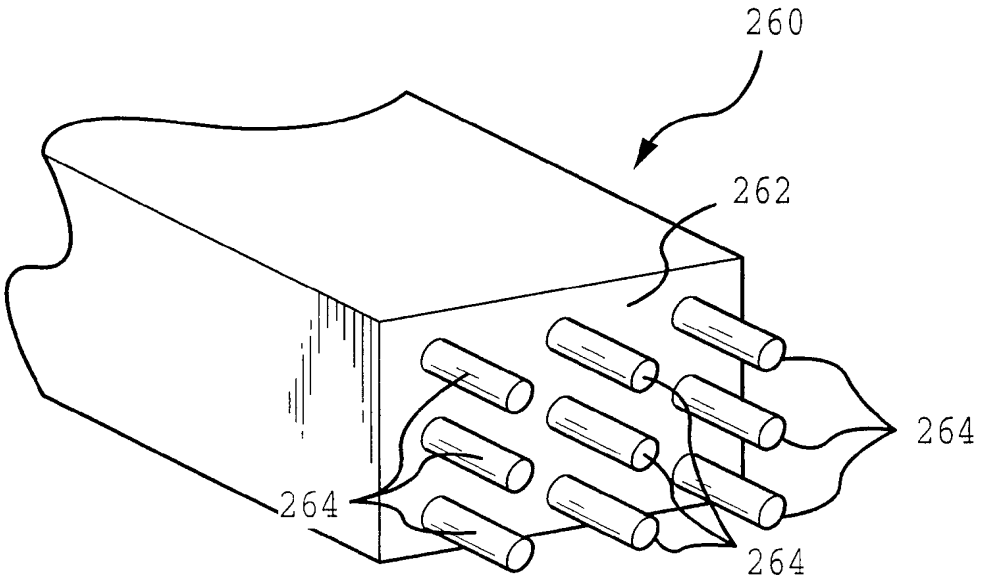

FIG.16

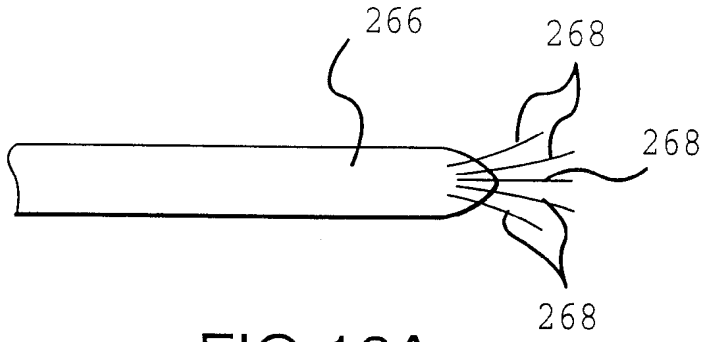

FIG.16A

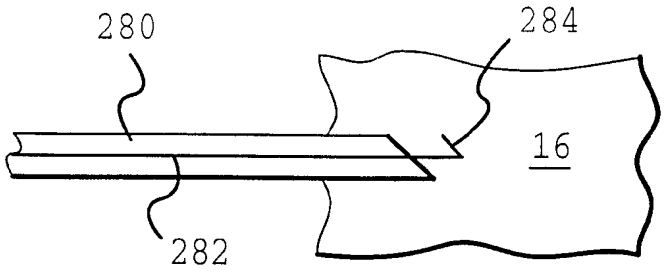

FIG.17

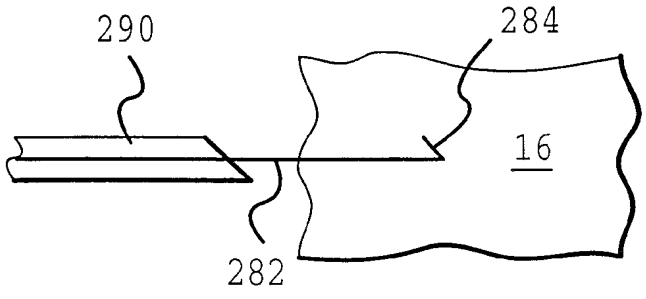

FIG.17A

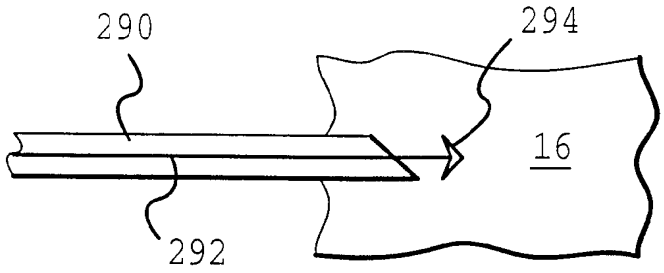

FIG.18

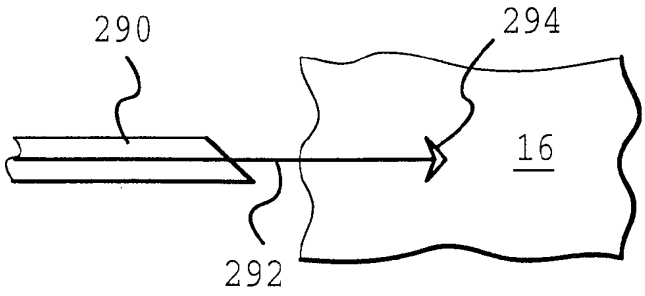

FIG.18A

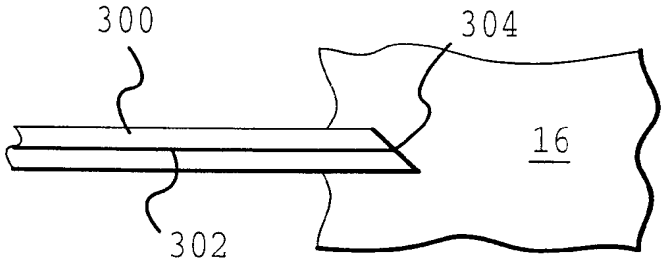

FIG.19

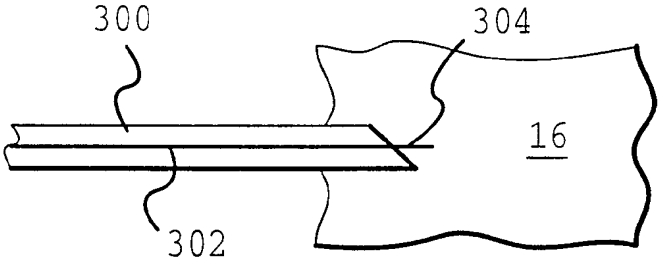

FIG.19A

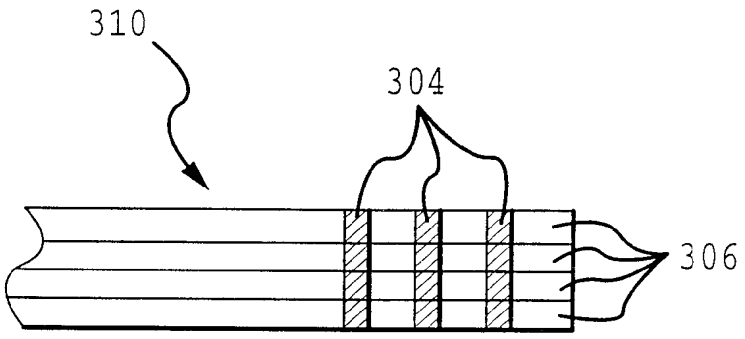

FIG.20

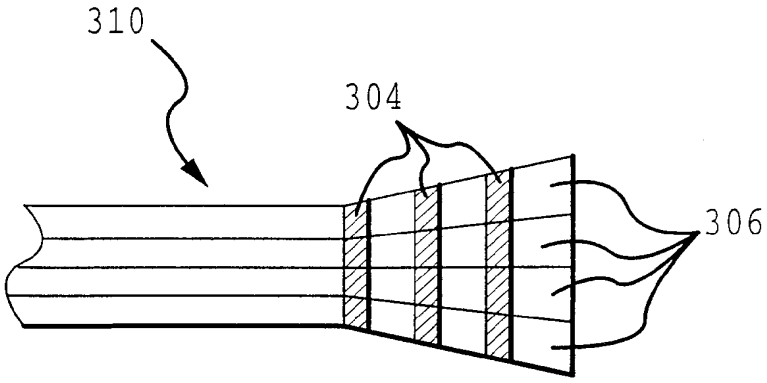

FIG.21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/24162

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/32
US CL :606/46, 52
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/40-48, 50, 52

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 5,441,499 A (FRITZSCH) 15 AUGUST 1995, SEE THE ENTIRE DOCUMENT.	1-3, 5, 8, 11, 14, 15, 19, 25, 27, 28 ——— 4, 6, 7, 9, 10, 12, 13, 16-18, 20-24, 26, 29-43

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 22 MARCH 1998	Date of mailing of the international search report 14 APR 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DAVID SHAY Telephone No. (703) 308-2215

Form PCT/ISA/210 (second sheet)(July 1992)★